

Propylene Glycol Monomethyl Ether

CAS #107-98-2

Swiss CD-1 mice, at 0.0, 0.5, 1.0, 2.0%, drinking water

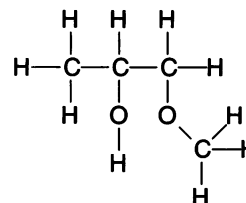
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NTIS: PB86170578/AS



Propylene glycol monomethyl ether (PGME), a solvent used in industry, was tested for reproductive toxicity in Swiss CD-1 mice using the RACB protocol (Morrissey et al., *Fundam Appl Toxicol* 13:747-777 [1989]). It was part of a series of glycol ethers and congeners evaluated for structure-activity correlations using this design. Data collected on body weights, clinical signs, and food/water consumption during the dose-range-finding segment (Task 1) were used to set concentrations for the main study (Task 2) at 0.5, 1.0, and 2.0% PGME in drinking water. These concentrations produced calculated consumption estimates of approximately 0.95, 1.9, and 3.3 g/kg/day.

During Task 2, no changes in body weight or water consumption were found in any of the exposure groups. There was

no reduction in the number of litters per pair, the number of live pups per litter, or the viability of those pups. Mean pup weight adjusted for litter size was reduced by 4% at the top dose level.

In the absence of an adverse effect on fertility, Task 3, the crossover test to identify the affected sex, was not conducted.

Task 4, the evaluation of the second generation, was conducted with the control and high dose groups only. The reduced pup weight at birth, noted in the first four litters, continued postnatally, with males and females weighing approximately 14% less than controls during nursing. Male body weights were approximately 8% lower than controls during the mating period, while female body weights during the mating period were not affected by PGME treatment. Mating and fertility indices were

unaffected by PGME, as were the number and viability of the F₂ offspring. After the F₂ pups were delivered, evaluated, and killed, the adult F₁ mice in the control and 2% PGME groups were killed and necropsied. While female body weight was not affected by PGME exposure, body weight-adjusted liver weight was increased by 7.5%. Male body weights in the 2% PGME group were 8% lower than controls, while relative epididymis and prostate weights were reduced by 9 and 8%, respectively.

In summary, there was some evidence of probable developmental toxicity, expressed as reduced pup weights, but no evidence of reproductive toxicity expressed as reduced litters or pup numbers. This F₁ pup weight effect was seen in the absence of an effect on F₀ adult body weight.

Summary: NTP Reproductive Assessment by Continuous Breeding Study.

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Chemical: Propylene Glycol Monomethyl Ether

CAS#: 107-98-2

Mode of exposure: Drinking water

Species/strain: Swiss CD-1 mice

F ₀ generation	Dose concentration →	0.5%	1.0%	2.0%
General toxicity		Male, female	Male, female	Male, female
Body weight		— , —	— , —	— , —
Kidney weight ^a		•	•	•
Liver weight ^a		•	•	•
Mortality		•	•	•
Feed consumption		•	•	•
Water consumption		— , —	— , —	— , —
Clinical signs		— , —	— , —	— , —

Reproductive toxicity			
\bar{x} litters/pair		—	—
# live pups/litter; pup wt./litter		— , —	— , ↓
Cumulative days to litter		—	—
Absolute testis, epididymis weight ^a		•	•
Sex accessory gland weight ^a (prostate, seminal vesicle)		•	•
Epidid. sperm parameters (#, motility, morphology)		•	•
Estrous cycle length		•	•

Determination of affected sex (crossover)	Male	Female	Both
Dose level	•	•	•

F ₁ generation	Dose concentration →	0.5%	1.0%	2.0%
General toxicity		Male, female	Male, female	Male, female
Pup growth to weaning		•	•	↓ , ↓
Mortality		•	•	— , —
Adult body weight		•	•	↓ , —
Kidney weight ^a		•	•	— , —
Liver weight ^a		•	•	— , ↑
Feed consumption		•	•	•
Water consumption		•	•	— , —
Clinical signs		•	•	— , —

Reproductive toxicity			
Fertility index		•	•
# live pups/litter; pup wt./litter		•	•
Absolute testis, epididymis weight ^a		•	•
Sex accessory gland weight ^a (prostate, seminal vesicle)		•	•
Epidid. sperm parameters (#, motility, morphology)		•	•
Estrous cycle length		•	•

Summary information
Affected sex? Unclear
Study confounders: None
F ₁ more sensitive than F ₀ ? No
Postnatal toxicity: Unclear

Legend: —, no change; •, no observation; ↑ or ↓, statistically significant change (p<0.05); — , —, no change in males or females. ^aAdjusted for body weight.